

Remarks

Claims 81-131 are presently pending in the subject application. Claims 1-29 and 77-80 have been additionally canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application. These claims have been canceled in favor of new claims 81-131, which are being presented to facilitate the Examiner's review. Reconsideration and allowance are respectfully requested in view of the above amendments and the following remarks.

New claim 81 is an independent detection probe claim that corresponds to prior claims 1 and 6 and provides that the base sequence of the target binding region of the probe is the base sequence of one of the recited sequences.

New claims 82-84 correspond to prior claims 10-12. New claim 82 provides that the target binding region consists of one of the recited sequences, but that the probe does not include additional regions capable of stably hybridizing to nucleic acid derived from *Trichomonas vaginalis* under stringent conditions. Uses of additional regions include those provided at page 21, lines 21-26, of the specification.

New claim 85 corresponds in part to prior claim 3 (probe length limitation).

New claim 86 corresponds to prior claim 9.

New claims 87-94 correspond to prior claims 13-20. New claim 93 recites that the base sequence of the helper probe consists of the base sequence of one of the recited sequences. New claim 94, like prior claim 20, is a withdrawn method claim but includes all of the limitations of new claim 81.

New claim 95 is an independent detection probe claim that corresponds to prior claims 21 and 27 and provides that a target binding region of the probe has one of the recited sequences corresponding to a core region targeted by the probe. *See* specification at page 5, lines 15-20.

New claim 96 corresponds to prior claim 31 and further provides that the target binding region is up to 30 bases in length, consistent with the maximum length of a disclosed probe containing a region which corresponds to the core region. *See* specification at page 5, lines 3-14.

New claims 97 and 98 correspond to prior claims 32 and 33, respectively.

New claim 99 corresponds in part to prior claim 23 (probe length limitation).

New claims 100, 102 and 104 recite that the base sequence of the probe consists of or is contained within one of the recited sequences (these claims require that the target binding region at least contain a base sequence corresponding to the core region). *See* specification at page 57, line 27 *et seq.*

New claims 101, 103 and 105 depend from claims 100, 102 and 104, respectively, and recite that the base sequence of the probe consists of one of the recited sequences.

New claims 106-111 correspond to prior claims 32-39. New claim 111, like prior claim 39, is withdrawn method claim but includes all of the limitations of new claim 95.

New claim 112 is kit claim that corresponds to prior claim 77 and depends from new claim 81. This claim provides that the target binding region of the capture probe has one of the recited sequences.

New claims 113-121 depend from claim 112 and recite various limitations set forth in the probe claims. Additionally, new claims 113 and 118 recite that the capture probe does not include regions in addition to the target binding region that are capable of stably hybridizing to nucleic acid derived from *Trichomonas vaginalis* under stringent conditions. *See* specification at page 26, line 38 *et seq.*

New claim 122 is a kit claim that corresponds to prior claim 79 and depends from new claim 95. This claim provides that the target binding region of the capture probe has one of the recited sequences.

New claims 123-131 depend from claim 122 and recite various limitations set forth in the probe claims. Additionally, new claim 123 recites that the capture probe does not include regions in addition to the target binding region that are capable of stably hybridizing to nucleic acid derived from *Trichomonas vaginalis* under stringent conditions. *See* specification at page 26, line 38 *et seq.*

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-19, 21-38 and 77-80 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for failing to satisfy the written description requirement. Applicants traverse this rejection for the reasons that follow. First, contrary to the Examiner's assertion, the amended claims identify the distinguishing attribute of the claimed probes as being the sequence of the target binding region. Second, although the Examiner has concluded otherwise, the structural identities of probes satisfying the functional requirements of the claimed probes (*e.g.*, hybridize to nucleic acid derived from *Trichomonas vaginalis* but not from *Trichomonas tenax*) are disclosed in the specification, certain embodiments of which are illustrated in the examples section. Thus, Applicants submit that the claims satisfy the written description requirement and, accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-19, 21-38 and 77-80 stand rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. In support of this rejection, the Examiner first contends that one skilled in the art would be unable to determine the metes and bounds of the claims from Applicants' use of the phrase "stringent hybridization conditions." Applicants disagree. For probes having sufficient complementarity to a target sequence and non-complementarity to non-target sequences, it is within the capabilities of those skilled in the art to establish stringent conditions without undue experimentation. The specification details some of the factors considered by those skilled in the art in determining appropriate conditions of stringency for a particular assay, and the examples section of the specification provides exemplary conditions for the probes of the present invention. Moreover, claims 90, 109, 116, 121 and 130, which correspond to prior claims 16 and 37, set forth particular temperature and salt conditions.

The Examiner next contends that it is unclear from Applicants' use of the phrase "derive from" in the claims whether the indicated nucleic acid is undergoing a chemical modification.

Applicants refer the Examiner to the definition of “derived” provided at page 26, lines 24-27, of the specification. From the definition, it is clear that the referred to nucleic acid is obtained directly from an organism or it is the product of an amplification reaction (e.g., an antisense RNA molecule that does not exist in nature).

For the reasons presented above, Applicants submit that the claims are definite. Accordingly, Applicants respectfully request withdrawal of the Examiner’s indefiniteness rejections.

Rejection Under 35 U.S.C. § 102

Claims 1-19 and 77 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated or, in the alternative, obvious over Matya *et al.* (J. Clin. Microbiol., 38(7):2683-2687 (2000)). Applicants submit that the amendments to the claims render moot the Examiner’s anticipation rejection and, further, that the Examiner has failed to set forth any basis for concluding that the presently pending claims are obvious. Accordingly, Applicants respectfully request withdrawal of the Examiner’s anticipation and obviousness rejections.

Applicants submit that the application is in condition for allowance and notice to that effect is hereby respectfully requested.

Reply Under 37 C.F.R. § 1.111
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Please charge any fees due in connection with this Reply, including the fee due for a two-month extension of time, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

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By: /Charles B. Cappellari/
Charles B. Cappellari
Registration No. 40,937
Attorney for Applicants

GEN-PROBE INCORPORATED
Patent Department/Mail Stop #1
10210 Genetic Center Drive
San Diego, California 92121
PH: 858-410-8927
FAX: 858-410-8928